REMARKS

Applicants respectfully request cancellation of claims 1-14 and 16-87 without prejudice. Claims 15 and 88-95 are pending in this patent application. Support for the added claims can be found in the specification at, for example, page 11, lines 4-9, pages 37-38, and in Figure 4.

Applicants believe that the issues attendant to allowance of their patent claims are relatively straightforward. In an effort to highlight these issues and streamline prosecution, Applicants have canceled a number of claims (without prejudice to their presentation in one or more continuing patent applications) in the hope that by doing so the patentability of the remaining claims will be even more apparent.

In discussing the above-noted claims during the interview, the Examiner questioned whether the Ritalin SR product that is disclosed in Patrick, *et al., Biopharmaceutics & Drug Disposition* **1989**, *10*, 165 ("the Patrick reference") would exhibit the claimed ascending release rate of methylphenidate over an extended period of time. Applicants' undersigned attorney noted that the Patrick reference appears to disclose plasma concentrations observed using the Ritalin SR product, and indicated that he would investigate whether release rate data could be obtained.

In a subsequent Office Action, the Examiner maintains her rejection of the claims under 35 U.S.C. § 103 in view of issues relating to whether the Patrick reference "teaches the ascending release form of methylphenidate" (Office Action dated May 7, 2003, at page 2).

Applicants hereby provide data which demonstrates that the Ritalin SR product that is disclosed in the Patrick reference does *not* exhibit the claimed ascending release rate profile over an extended period of time. In fact, as is discussed in the accompanying declaration of

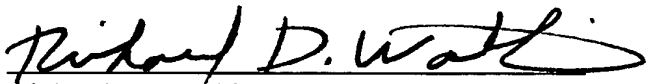
inventor Suneel Gupta, the rate at which the Ritalin SR product releases methylphenidate actually *decreases* over an extended period of time. Dr. Gupta supervised an analysis of the Patrick reference's reported plasma concentration data using the Wagner-Nelson deconvolution technique (Gupta Declaration, at ¶ 3). This type of data analysis, which is routinely performed by those skilled in the art (*id.*), approximates the release rate that the Ritalin SR product would have needed to achieve to produce the plasma concentrations that are reported in the Patrick reference (*id.* at ¶ 4). As indicated by Dr. Gupta, this model clearly shows that the Ritalin SR release rate does not ascend over an extended period of time but, rather, decreases (*id.* at ¶ 5).

Since the instant rejection of Applicants' claims was based on an alleged teaching of ascending release rates in the Patrick reference – and since that teaching is not, in fact, present, Applicants respectfully request that the rejection be withdrawn. Indeed, to the extent that the teaching of the Patrick reference would have been relevant to persons of ordinary skill, it would have led such persons *away from* the claimed inventions.

Applicants invite the Examiner to contact their undersigned representative if any questions arise or further information regarding the instant patent application is needed. In

view of the foregoing, however, Applicants submit that the pending claims are in condition for ready allowance, and therefore respectfully request an early indication of allowability.

Date: August 4, 2003



Richard D. Watkins
Registration No. 50,993

Joseph Lucci
Registration No. 33,307

Woodcock Washburn LLP
One Liberty Place - 46th Floor
Philadelphia PA 19103
Telephone: (215) 568-3100
Facsimile: (215) 568-3439